

With respect to the objection to certain language in claim 7(b), claim 7 has been amended, as set forth above. The language objected to by the Examiner was "a portion of HER-2/*neu* protein." Claim 7 (and claims 8 and 9) has been amended to delete "a portion" and to clarify that all of the amino acids of the sequence have correspondence to those found in HER-2/*neu* protein. Claim 7 (and claims 8 and 9) further requires that a DNA sequence according to part (b) of the claim, encode a polypeptide which is at least approximately the same length as the polypeptide encoded by the DNA sequence of part (a). The polypeptide encoded by the DNA sequence of part (a) is 580 amino acids in length. Applicants' prior related applications have described peptides which are located throughout the full length sequence and which elicit or enhance an immune response to HER-2/*neu*. For example, Applicants' U.S. Patent No. 5,801,005 (matured from U.S. Serial No. 414,417 which is listed at page 1, line 9, of the subject application as filed) describes such peptides (i.e., small fragments) of full length HER-2/*neu* protein. Thus, given the length requirement in claim 7 (and claims 8 and 9), amended claims 7-12 are sufficiently definite within the meaning of Section 112, second paragraph.

Therefore, Applicants believe that the rejection of claims 7-12 under 35 U.S.C. § 112, second paragraph, has been overcome. Withdrawal of this objection is respectfully requested.

In the Office Action, claims 8-12 were rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement for the term "cells". This rejection is respectfully traversed.

At page 2 of the Office Action, it is agreed that the methods are enabled for transfecting or infecting antigen presenting cells. However, it is asserted that the methods are not enabled for the use of non-antigen presenting cells. Applicants respectfully disagree.

Nevertheless, in order to expedite prosecution, claims 8 and 9 (and thus claims 10-12 which depend therefrom) have been amended to specify that the cells are antigen presenting cells. Accordingly, without conceding the issue of patentability of claims 8-12 as originally filed, amended claims 8-12 satisfy the requirements of Section 112, first paragraph.

Therefore, Applicants believe that the rejection of claims 8-12 under 35 U.S.C. § 112, first paragraph, has been overcome. Withdrawal of this rejection is respectfully requested.

Therefore, in light of the amendments and remarks set forth above, Applicants believe all the Examiner's rejections have been overcome. Reconsideration of the application and allowance of all pending claims (7-12) are respectfully requested. If there is any further matter requiring attention prior to allowance of the subject application, the Examiner is respectfully requested to contact the undersigned attorney (at 206-622-4900) to resolve the matter. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version With Markings to Show Changes Made.**"



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PATENT TRADEMARK OFFICE

Respectfully submitted,

Seed Intellectual Property Law Group PLLC

A handwritten signature in black ink, appearing to read "Richard G. Sharkey", written over a horizontal line.

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Enclosure:

Postcard

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 7 has been amended as follows:

7. (Thrice Amended) A method for eliciting or enhancing an immune response to ~~HER-2/neu~~ HER-2/neu protein, comprising administering to a warm-blooded animal in an amount effective to elicit or enhance said response a nucleic acid molecule or a viral vector wherein the nucleic acid molecule or the viral vector directs the expression of a polypeptide encoded by a DNA sequence selected from:

- (a) nucleotides 2026 through 3765 of SEQ ID NO:1; and
- (b) DNA sequences that hybridize to a nucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1 under moderately stringent conditions, wherein the DNA sequence encodes a polypeptide that produces an immune response to HER-2/neu protein and ~~that possesses an whose entire amino acid sequence which is identical to a portion of~~ from HER-2/neu protein and which is at least approximately the same length as the polypeptide encoded by the DNA sequence of (a).

Claim 8 has been amended as follows:

8. (Amended) ~~A method according to claim 7 wherein the step of administering comprises~~ A method for eliciting or enhancing an immune response to HER-2/neu protein, comprising ~~transfecting antigen presenting cells of the animal~~ a warm-blooded animal ex vivo with the ~~a~~ nucleic acid molecule and subsequently delivering the transfected cells to the animal in an amount effective to elicit or enhance said response, wherein the nucleic acid molecule directs the expression of a polypeptide encoded by a DNA sequence selected from:

- (a) nucleotides 2026 through 3765 of SEQ ID NO:1; and
- (b) DNA sequences that hybridize to a nucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1 under moderately stringent conditions, wherein the DNA sequence encodes a polypeptide that produces an immune response to HER-2/neu protein and whose entire amino acid sequence is from HER-2/neu protein and which is at least approximately the same length as the polypeptide encoded by the DNA sequence of (a).

Claim 9 has been amended as follows:

9. (Amended) ~~A method according to claim 7 wherein the step of administering comprises~~ A method for eliciting or enhancing an immune response to HER-2/neu protein, comprising infecting antigen presenting cells of the animal a warm-blooded animal *ex vivo* with the a viral vector and subsequently delivering the infected cells to the animal in an amount effective to elicit or enhance said response, wherein the viral vector directs the expression of a polypeptide encoded by a DNA sequence selected from:

(a) nucleotides 2026 through 3765 of SEQ ID NO:1; and

(b) DNA sequences that hybridize to a nucleotide sequence complementary to nucleotides 2026 through 3765 of SEQ ID NO:1 under moderately stringent conditions, wherein the DNA sequence encodes a polypeptide that produces an immune response to HER-2/neu protein and whose entire amino acid sequence is from HER-2/neu protein and which is at least approximately the same length as the polypeptide encoded by the DNA sequence of (a).